



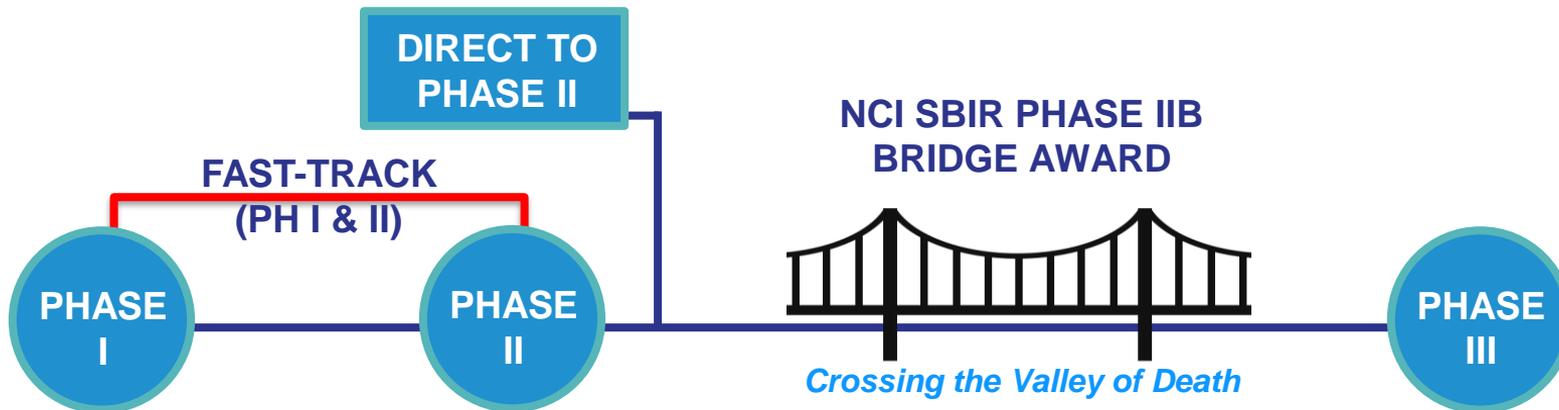
NCI SBIR “HIGH-RISK HIGH-REWARD” INNOVATIVE CONCEPT AWARD

RFP Concept Review

Presented to BSA

**Presented by
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May 11, 2020**

THREE-PHASE PROGRAM



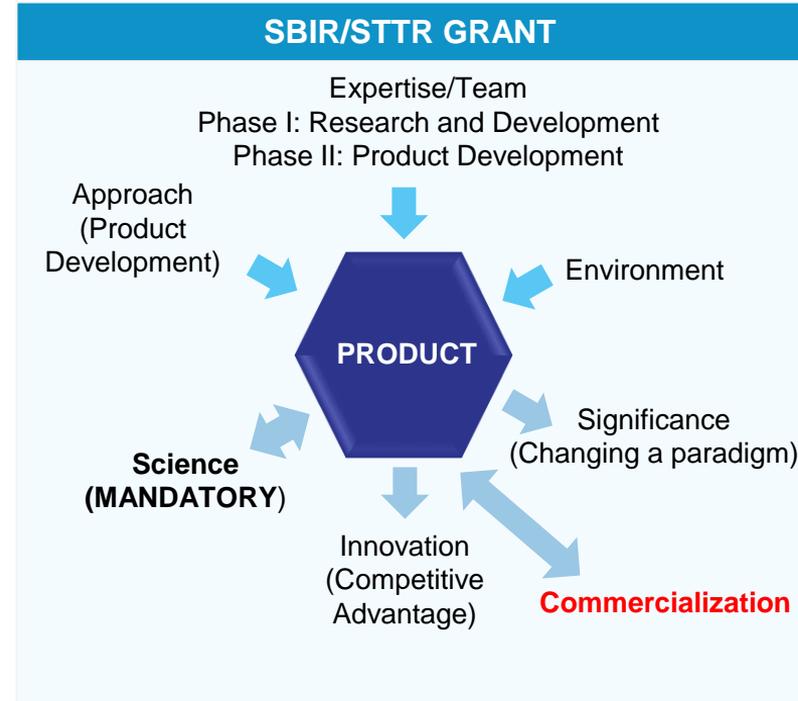
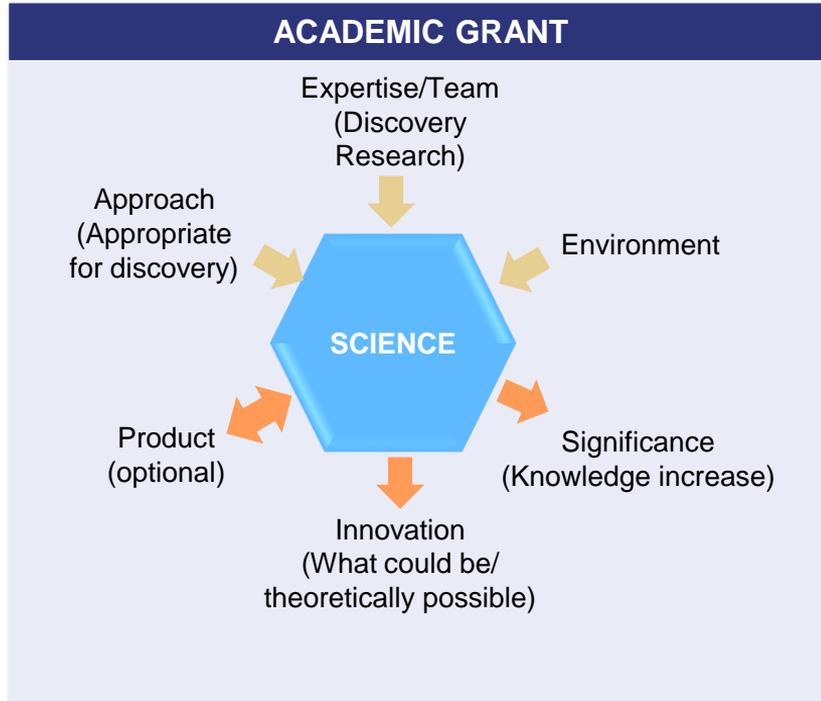
- Proof-of-Concept
- **Up to \$400K over 6 to 12 months**

- Research & Development
- Commercialization plan required
- **Up to \$2M over 2 years**

- Technology validation & clinical translation
- Follow-on funding for SBIR Phase II awardees from any federal agencies
- Expectation that applicants will secure substantial third party investor funds
- **\$4M over 3 years**

- Commercialization stage
- Use of non-SBIR/STTR funds

SBIR/STTR vs. ACADEMIC GRANTS





NCAB WORKING GROUP REPORT ON THE NATIONAL CANCER INSTITUTE SMALL BUSINESS INNOVATION RESEARCH PROGRAM

February 2019

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PRIORITY GOALS FOR NCI SBIR/STTR

❖ Implement SBIR “Concept grant”

- ❖ Use supplements to advance companies to value-creating milestones
- ❖ Develop FDA regulatory assistance program
- ❖ Develop postdoctoral training program in entrepreneurship and tech transfer
- ❖ Continue and enhance metrics collection
- ❖ Promote diversity
- ❖ Reduce time-to-award for SBIR contracts
- ❖ Increase Phase I award size

Launch SBIR Concept Award

- Support high-risk/high-reward technologies in targeted areas
- De-risk projects
- Short applications
- Preliminary data are not required.
- Make awards rapidly (within six months).
- Leverage I-Corps at NIH Program
- Followed by another Phase I, Direct to Phase II or Fast-Track

GOAL OF SOLICITATION

Encourage small businesses to develop :

- **high risk/high impact** technologies
- Disruptive innovation
- Pre-SBIR/Phase “0”
- Product-focused projects
- Focus areas
 - pediatric or rare cancers.

What is innovative?

- Development of ground-breaking new products, technologies or tools
- Disruptive innovation rather than incremental innovation
- Transformative technologies with the potential to change clinical care

What is NOT innovative?

- Therapeutics targeting known pathways with FDA-approved agents
- Technologies in clinical stage or already far down the development pathway
- Continuation of already funded SBIR/STTR projects

CONCEPT AWARD: NCI SBIR CONTRACTS

PURPOSE

Support small businesses developing highly innovative and transformative technologies that have the potential to create new scientific paradigms, establish entirely new and improved clinical approaches to significantly improve cancer research, prevention, detection and care for pediatric or rare cancers.

IMPORTANT POINTS

- Short Application
- Faster Turn around (<6 months)
- No preliminary data required
- Applicants encouraged to go through I-Corps at NIH
- Followed by another Phase I, Direct to Phase II or Fast-Track

FOA

- RFP- 3 year pilot
- Phase I only, clinical trials not allowed
- Only one receipt date per year in pilot period
- Estimated awards per year/per round: 5-10
- Estimated cost per year: \$1.5M - \$3M

BUDGET

- \$300K total costs
- 1 year award

ELIGIBILITY

- Must be a small business
- At least 66% of the work must be done by the small business

PILOT FOCUS AREA: PEDIATRIC CANCERS

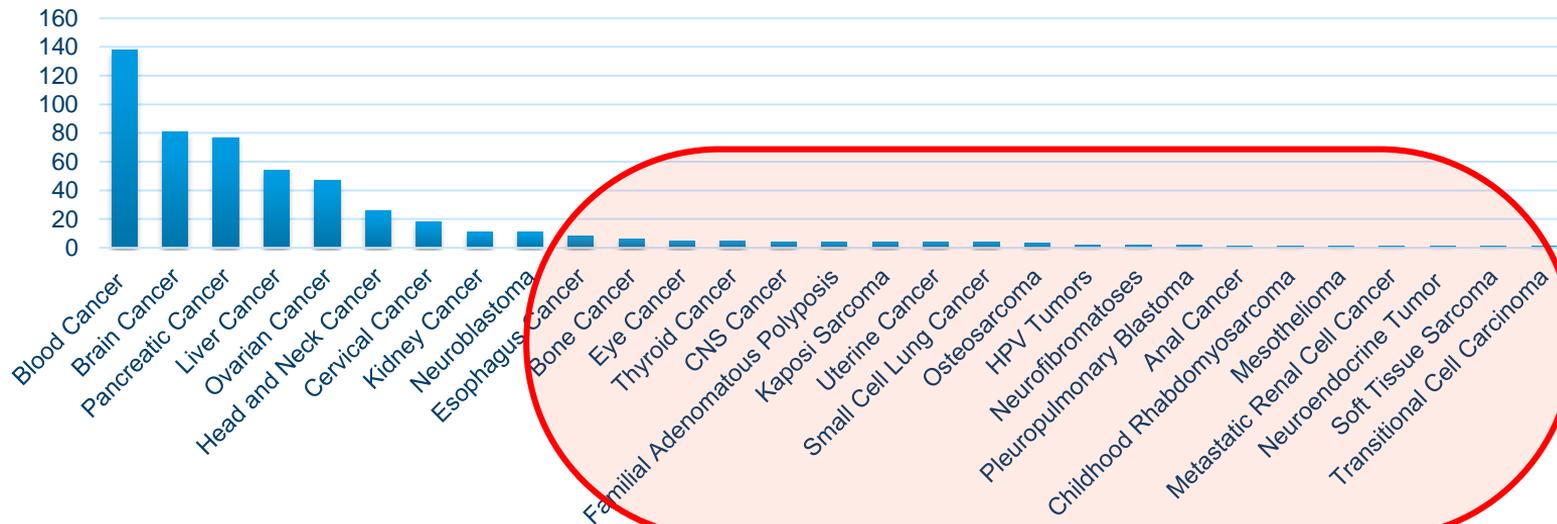
- Only 12 were new molecular entities intended to treat cancer seen primarily in children in last 25 years.
- Private investment in pediatric cancer is low.

NCI SBIR Awards focused on pediatric cancer (2010-2018)

Type	Number of Competing Awards
Can be used for pediatric cancer	26
Specifically for pediatric cancer	20
Total	46

PILOT FOCUS AREA: RARE CANCERS

Number of Competing Awards



- Rare cancer defined as: www.rare-cancer.org/info/raw-adult-list.php
 - <http://obroncology.com/article/rare-cancers-are-no-longer-orphans/>
 - <http://www.cancer.net/blog/2019-01/progress-treating-rare-cancers-2019-advance-year>

EXAMPLES OF PROJECTS/ACTIVITIES

Therapeutics

- New mechanism of action
- New targets

Devices

- Innovative drug delivery tools

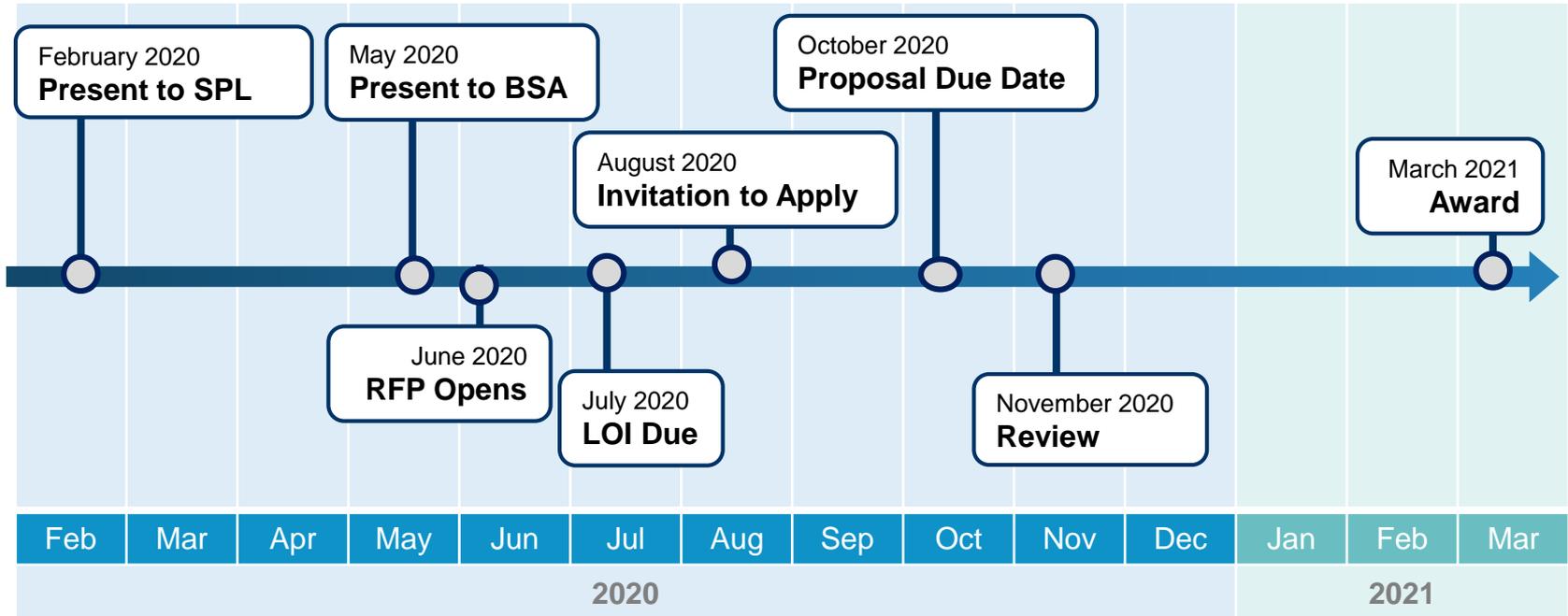
Diagnostics

- AI Driven prognostics/
diagnostics tool

WHY SBIR CONTRACT MECHANISM?

- **Application**
 - Shorter proposal (up to 15-20 pages max with up to 3 pages for research strategy)
 - Modify proposal (application) components
 - 1-2 page **Letter of Intent** to be reviewed for responsiveness by NCI PDs
- **Review**
 - Focus on Innovation/Special Review Criteria and Panel
 - Ability to modify review criteria weightage unlike the omnibus grant mechanism
 - Assess scientific rationale given the preliminary data
 - **NCI DEA Special Review Panel** with mix of academic industry venture and biotech
- **Milestone-driven**
 - Quarterly reporting
 - Payment based on achieving milestones

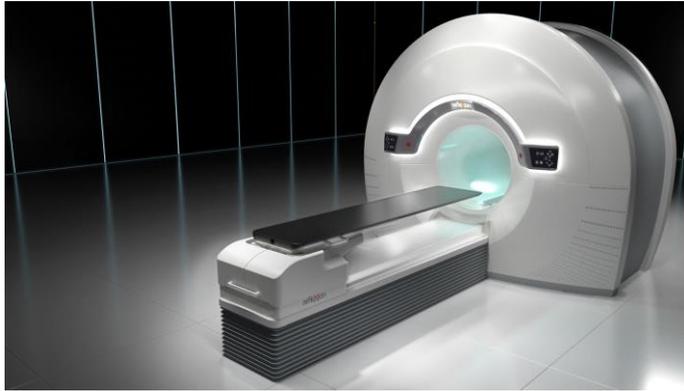
TIMELINE



16 / 0,32
160 / 0,17

THE END

EXAMPLE : REFLEXION MEDICAL



Biologically Guided Radiation Therapy - Combine PET Imaging and LINAC

See & Treat Mechanism

Treat multiple tumors or metastasis in one treatment session

NCI SBIR funded them at early concept stage with no preliminary data.

Right now raised over \$100M, will be in clinic in the next 2 months

Excellent team

Examples of Activities & Deliverables

Budget: Phase I \$300,000 for up to 9-12 months

Activities & Deliverables could include:

- Identify and define the clinical need that the product or technology will address.
- Obtain feasibility data/ proof of concept data that the proposed product or technology can solve a significant unmet need in pediatric/rare cancers.
 - Therapeutics: Validation of a novel target; identification and development of a lead compound; *in vitro* and/or *in vivo* efficacy studies
 - Medical Devices: Evaluation and validation of clinical need; development of a prototype or minimal viable product; phantom and/or *in vivo* safety and/or efficacy studies
 - Diagnostics: Biomarker discovery and validation; assay development and optimization; define assay performance and analytic validation
- Identify next steps and develop a product development plan (to be pursued under a future SBIR Phase I or Phase II award)